Instructions for Completing the Serious Preventable Adverse Event Report Form

The Report of Serious Preventable Adverse Event in A New Jersey General Hospital Form is to be completed and transmitted only by an authorized facility representative. Completed forms are to be FAXED to the Department at (609) 530-4850 within two (2) Department business days of the discovery of the serious preventable adverse event, but in no case later than five (5) days after the occurrence of the event. The only exception pertains to objects erroneously retained in a patient after surgery, where the standard is no later than two (2) Department business days after discovery. Department business days mean Monday – Friday except for State holidays.

NOTE: A serious preventable adverse event is deemed *reported* to the Department only when the form is completed AND has been received by the Patient Safety Reporting Initiative. The Department will confirm receipt of the transmission by return Email or fax. Updated versions of the form may be submitted if new information becomes available. Updated forms should include all information, indicating which fields are revised.

COMPLETING THE FORM

Please Type or Print All Information

- Indicate whether this is the first report of this event or a revision.
- IF a revision, give the DHSS Report Number which was assigned with the confirmation of receipt of the initial report from the Patient Safety Reporting Initiative.

NOTE: The Department anticipates that, to meet the reporting time frame, initial reports may be only partially complete and will be supplemented by updates.

SECTION A - GENERAL INFORMATION

1. Facility Identification

- List facility name, full address, and State of NJ license number.
- List the name, title, and contact information of the person completing the form.

2. Description of the Event

- Provide a short description of the event in narrative form, including how the event occurred and any medications, equipment, or conditions involved in the event.
- List the date and time of the event (note: if the event involves a surgical procedure, indicate the time that the procedure began).
- List the date and time the event was discovered.
- If the time of the event is unknown, list the time as "unknown."

3. How Was the Event Discovered?

- Indicate how the event was discovered.
- If "other" is checked, provide a brief description of how the event was discovered.

4. Patient Information

Provide the following information about the patient:

- Indicate whether the patient received inpatient or outpatient care.
- Indicate how the patient was admitted (Emergency Department, Direct Admission, or Transfer from another facility). List the patient's billing number, the unique identifier for each admission.
- List the patient's medical record number or other identification used by the facility.
- List the patient's name and full address.
- List the patient's date of birth and gender.
- List the date of patient's admission to the facility or date of ambulatory encounter.
- List the patient's primary diagnosis, if applicable.
- Indicate the race and ethnicity of the patient, if known.
- If "other" is checked, provide a brief description of the race or ethnicity.

5. Types of Serious Preventable Adverse Events

Using the definitions below, indicate the general classification and type of the serious preventable adverse event. Use only one category.

- A. Care management-related events include, but are not limited to:
 - Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, wrong route of administration, etc.);
 - Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;
 - Maternal death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with labor or delivery in a low- risk pregnancy while in a health care facility;
 - 4. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the health care facility;
 - 5. Death or kernicterus associated with failure to identify and treat hyperbilirubinemia in a neonate while the neonate is a patient in a health care facility;
 - Stage three or four pressure ulcers acquired after admission of the patient to a health care facility. Excludes progression from Stage two to Stage three if Stage two was recognized upon admission;

- 7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility;
- 8. Other patient care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

B. Environmental events include, but are not limited to:

- Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with an electric shock while being cared for in a health care facility. Excludes events involving planned treatments, such as electric counter shock (heart stimulation);
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances and results in patient death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge;
- 3. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a burn incurred from any source while in a health care facility;
- 4. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a fall while in a health care facility;
- 5. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with the use of restraints or bedrails while in a health care facility;
- 6. Other environmentally-related adverse preventable events resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

C. Product or device-related events include, but are not limited to:

- Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product;
- 2. Use or function of a device in patient care in which the device is used or functions other than as intended, including but not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators;
- Intravascular air embolism that occurs while the patient is in the facility.
 However, this does not include deaths or disability associated with
 neurosurgical procedures known to present a high risk of intravascular air
 embolism:

4. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

D. Surgery-related events include, but are not limited to:

- 1. Surgery initiated (whether or not completed) on the wrong body part;
- 2. A surgical procedure (whether or not completed) intended for a different patient of the facility, but initiated on this patient;
- 3. A wrong surgical procedure initiated (whether or not completed) on a patient;
- 4. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained;
- 5. Inter-operative or post-operative (i.e. within twelve hours) coma, death or other serious preventable adverse event for any ASA Class I inpatient or any same day surgery patient (all ASA classes). Includes all patient deaths, comas or other serious preventable adverse events in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out;
- Other surgery-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

E. Patient protection-related events include, but are not limited to:

- 1. Discharge of an infant to the wrong person, excluding patient abductions;
- 2. Any patient death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient elopement;
- 3. Patient suicide or attempted suicide while in a health care facility. However, this does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility;
- 4. Other patient protection-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge not included within the definitions above.

6. For Medication Errors Only

- If 5.A.1 is checked, indicate the type of medication error.
- If "other" is checked, provide a short description of the medication error.
- List the brand name and/or generic name of the medication.

7. Where Was the Patient When the Event Occurred?

- Indicate the location of the patient when the event occurred. Check only one location.
- If "other" is checked, provide a short description of the location.

8. Immediate Corrective Action(s) Taken

 Provide a description of the immediate corrective action taken in response to the event. The description provided should include the specific procedures implemented, if any, to reduce the likelihood of recurrence of this event. List any additional reports provided to other organizations or agencies (e.g., equipment manufacturers, pharmaceutical manufacturers, and professional oversight boards) concerning this event.